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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/520,419 | 03/08/2000 | Julie A. Meek | 9110-0008 | 1596 |

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| EXAMINER | |
| BLECK, CAROLYN M | |
| ART UNIT | PAPER NUMBER |

3626

DATE MAILED: 02/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/520,419 | MEEK ET AL. |
| | Examiner | Art Unit |
| | Carolyn M Bleck | 3626 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 December 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-27 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 5 December 2002. Claims 1-4 and 6-20 remain pending. Claim 5 has been amended. Claims 21-27 are newly added.

Claim Objections

2. Claim 25 is objected to because of the following informalities: "...predetermined level with a prospective time span..." line 2, claim 25, appears to be grammatically incorrect. Appropriate correction is requested.

Specification

3. The amendment filed 5 December 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The newly recited claims 21-27 appear to constitute new matter.

In particular, Applicant does not point to, nor was the Examiner able to find, any support for this newly added language within the specification as originally filed. As such, Applicant is respectfully requested to clarify the above issues and to specifically

point out support for the newly added limitations in the originally filed specification and claims.

Applicant is required to cancel the new matter in the reply to this Office Action.

4. If Applicant continues to prosecute the application, revision of the specification and claims to present the application in proper form is required. While an application can be amended to make it clearly understandable, no subject matter can be added that was not disclosed in the application as originally filed.

Claim Rejections - 35 USC § 112

5. Claims 21-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A) Dependent claims 21-27 recite limitations that are new matter, as discussed above, and are therefore rejected.

NOTE: The following rejections of claims 21-27 assume that the subject matter added in the 5 December 2002 amendment are not new matter, and are provided hereinbelow for Applicant's consideration, on the condition that Applicant properly traverses the new matter objections and rejections made in sections 3-5 above in the next communication sent in response to the present Office Action.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 5, 8-11, 14-16, 19, and 21-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al. (5,976,082), for substantially the same reasons given in the previous Office Action (paper number 5). Further reasons appear hereinbelow.

(A) Claims 1, 8-11, 14-16, and 19 have not been amended and are rejected for the same reasons given in the previous Office Action (paper number 5), and incorporated herein.

(B) The amendments to claim 5 appear to have been made to merely correct grammatical errors, but otherwise do not affect the scope and breadth of the claim as originally presented and/or in the manner in which the claim was interpreted by the Examiner when applying prior art within the previous Office Action.

As such, the recited claimed features are rejected for the same reasons given in the prior Office Action (paper number 5, section 3(b), pages 3-4), and incorporated herein.

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(C) As per claims 21-27, Wong discloses:

(a) determining a resulting subset of variables from a set of variables or predictors best reflecting a correlation to patients who are at high risk for adverse health outcomes, consequently, resulting in substantial use of health care resources (e.g., funds) (Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 38-61, col. 3 lines 58-67, col. 4 lines 24-34, col. 4 line 61 to col. 5 line 25, col. 5 line 66 to col. 6 line 16, col. 6 lines 44-51, col. 7 lines 12-21, col. 8 line 65 to col. 9 line 5, and col. 17 line 49 to col. 18 line 4); and

(b) defining points A, B, and C, wherein A represents the farthest past event, wherein B represents the present, wherein C can be defined by the last day for which an individual is still enrolled and eligible for benefits within a health plan, wherein A<B<C, and wherein the prediction of congestive heart failure hospitalization includes defining a time period between B and C such as 6 months used to predict CHF hospitalization within the next 6 months (col. 13 line 48 to col. 14 line 48). It is noted that the prediction time period of 6 months as discussed above in Wong is a "prospective time span."

The remainder of claims 21-23 repeat the same limitations as claim 1, and are therefore rejected for the same reasons given for those claims, and incorporated herein.

Claims 24-27 repeat the same limitations as claims 21-23, and are therefore rejected for the same reasons given for those claims, and incorporated herein.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 2-3 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (5,976,082) as applied to claim 1 and 16 above, and further in view of Mebane (5,486,999), for substantially the same reasons given in the previous Office Action (paper number 5). Further reasons appear hereinbelow.

(A) Claims 2-3 and 17 have not been amended and are rejected for the same reasons given in the previous Office Action (paper number 5), and incorporated herein.

10. Claim 4, 12-13, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (5,976,082) as applied to claim 1, 11, and 16 above, and further in view of Silver (6,269,339), for substantially the same reasons given in the previous Office Action (paper number 5). Further reasons appear hereinbelow.

(A) Claims 4, 12-13, and 18 have not been amended and are rejected for the same reasons given in the previous Office Action (paper number 5), and incorporated herein.

11. Claims 6-7 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (5,976,082) as applied to claim 1 and 16, for substantially the same

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reasons given in the previous Office Action (paper number 5). Further reasons appear hereinbelow.

(A) Claims 6-7 and 20 have not been amended and are rejected for the same reasons given in the previous Office Action (paper number 5), and incorporated herein.

Response to Arguments

12. Applicant's arguments filed 5 December 2002 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 5 December 2002.

(A) At pages 4-6 of the 5 December 2002 response, Applicant argues that various features recited in claim 1 are not taught by the applied reference. In particular, Applicant argues that "generating... a risk level of the individual utilizing healthcare services at a predetermined level within a prospective time span." Further, Applicant argues that "patient records" do not equate or read on "individuals."

In response, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 5 December 2002 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the teachings of Wong and collective teachings of Wong, Mebane, and/or Silver, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given

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the preceding sections of the present Office Action and in the prior Office Action (see paper number 3), and incorporated herein.

With respect to Applicant's argument that the applied reference fails to disclose "generating... a risk level of the individual utilizing healthcare services at a predetermined level within a prospective time span," as recited in claim 1, it is respectfully submitted that Applicant ignores the teachings of Wong with respect to receiving (reads on "collecting"), storing, and extracting information from a patient record (reads on "individual") for a predetermined set of criteria or predictors, assigning, based upon information from a patient record, a separate value to each predictor of the set of predetermined criteria or predictors, and generating, based upon a prediction model and the separate values assigned to the predetermined set of criteria or predictors, risk subgroups (reads on "risk level") of the patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (Fig. 1A-1B, 4, and 6A-6B, Abstract lines 1-24, col. 1 lines 48-60, col. 2 lines 38-67, col. 3 lines 1-7, col. 3 lines 42-67, col. 4 line 24 to col. 5 line 12, col. 5 lines 13-25, col. 5 line 66 to col. 6 line 16, col. 6 lines 44-67, col. 7 lines 12-21, col. 8 lines 18-35, col. 12 lines 7-39, col. 13 lines 1-60, col. 17 line 49 to col. 18 line 4, and col. 18 lines 15-23 and lines 28-41). Further, Wong discloses defining points A, B, and C, wherein A represents the farthest past event, wherein B represents the present, wherein C can be defined by the last day for which an individual is still enrolled and eligible for benefits within a health plan, wherein A<B<C, and wherein the prediction of congestive heart failure hospitalization includes defining a time period between B and C such as 6

months used to predict CHF hospitalization within the next 6 months (col. 13 line 48 to col. 14 line 48). It is noted that the prediction time period of 6 months as discussed above in Wong is a "prospective time span."

In response to Applicant's argument that "patient records" do not equate or read on "individuals," the Examiner respectfully submits a patient record contains information about or from a specific patient, such as data of birth, gender, and diagnoses and treatments (Wong; col. 8 lines 40-60), and a patient record clearly provides information from an individual. Applicant does not point to any specific language within claim 1 that positively and definitely distinguishes Applicant's collecting information from an individual from the prior art teachings of Wong as discussed above. Further, there is no express recitation of collecting information from a questionnaire in claim 1. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

(B) Applicant's remaining arguments given at pages 6-7 of the response filed 5 December 2002 rely upon or re-hash the issues addressed above, and are therefore moot in view of the responses given in section 12(A) above, and incorporated herein.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to the Applicant's disclosure. The cited but not applied prior art teaches a method and system for providing a comprehensive healthcare assessment and planning (6,484,144).

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-3981. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (703) 305-9588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 306-1113.

16. Any response to this action should be mailed to:

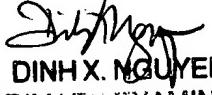
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

- | | |
|----------------|--|
| (703) 305-7687 | [Official communications; including After Final communications labeled "Box AF"] |
| (703) 746-8374 | [Informal/ Draft communications, labeled "PROPOSED" or "DRAFT"] |

Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor (Receptionist).

CB
January 29, 2003


DINH X. NGUYEN
PRIMARY EXAMINER